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Montana Board of Pharmacy

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PO Box 200513, 301 S Park Ave, 4th Floor
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Pseudoephedrine

As of July 1, 2005, only pharmacies may sell over-the-counter drug products in which pseudoephedrine is the only active ingredient or any solid dosage form containing pseudoephedrine regardless of other ingredients.

- These products must be stored behind the counter or in a locked case so that a customer is required to ask a pharmacy employee for assistance.
- Sales must be limited to no more than a total of 9 grams in any 30-day period, records must be kept for two years, and pharmacies must provide access to sales records if requested by law enforcement officials.
- Customers purchasing these products must have a driver's license or other form of photo identification and sign a record of sale that includes the **date** of the transaction, the **name of the person**, and the **number of grams** of the product purchased. A simple log book containing the above information will suffice.

Convenience stores will be allowed to sell **liquids, gel caps, and liquid capsules** in which pseudoephedrine is **not the only active ingredient** subject to the above restrictions. We apologize for the short notice. Senate Bill (SB) 287, which mandated these changes, was signed into law late in April 2005. SB 287 was not a Montana Board of Pharmacy bill, although it was a good step toward decreasing methamphetamine (meth) production within our state. An estimated 20% of meth used in Montana is manufactured within our borders. SB 287 and related information is located on the Board's Web site at www.discoveringmontana.com/dli/pha.

Highlights of Proposed Rule Changes

A 34-page rule notice will be available for public comment in July or August 2005. The entire document will be available on the Board's Web site at www.discoveringmontana.com/dli/pha or can be mailed upon request by calling the Board office at 406/841-2356. Many of the changes are housekeeping matters, but important substantive changes are also proposed:

- A rule to enable the practice of telepharmacy in Montana, utilizing registered pharmacy technicians at the remote site subject to rules protecting patient safety, confidentiality, and pharmacy security, is proposed. It is important to note that provision of best-practice pharmacy service in underserved areas, not economic concerns, is the driving force behind this proposed rule. The rule also proposes that a remote site cannot be licensed if it is located within a 10-mile radius of an existing pharmacy. A similar rule utilizing a registered technician and a computerized dispensing machine together at the remote site is also proposed. It is hoped that additional telepharmacy wording will be proposed in the future to address the needs of institutional pharmacy in our rural state as well.
- Central filling would allow two licensed pharmacies, staffed by registered pharmacists, to enter into an agreement allowing the hub, or central pharmacy to fill prescriptions and transfer the filled prescriptions securely back to the remote site. Patient counseling by the pharmacist could occur at either site. This would enable greater flexibility in pharmacy practice.
- It is necessary for the Board to be able to contact all licensees for renewal, rulemaking notification, and disciplinary purposes. A rule amendment to include pharmacy technicians under reporting requirements is proposed, plus wording that would clarify which address changes should be reported to the Board.
- Another proposal would allow pharmacy interns who have received training and certification from a Board-approved program to perform immunizations while under the direct supervision of a qualified pharmacist.
- Electronic prescription transfer should not only be more efficient, but also have the potential to protect public health and safety as transcription errors are avoided. The procedures for manual and electronic transfer differ in several ways, and have been separated into two distinct sections.
- With advances in electronic prescribing technology, many programs must route electronic messages through a secure switching station. Providing patient confidentiality and freedom of choice of pharmacy by the patient is ensured and the prescription is not altered in any way on its electronic path from prescriber to pharmacy; the Board has no objection to systems requiring electronic re-routing during transmission. Any arrangement that would limit the patient's ability to have a prescription filled at the pharmacy of their choice is still prohibited and subject to disciplinary action.

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New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.

Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

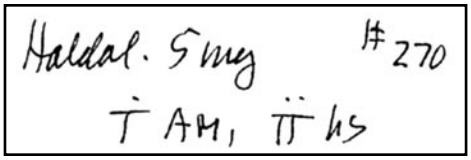
Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for

the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as "phenobarbital 32.400MG tablet." The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily. The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.



Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- Always include a leading zero for dosage strengths or concentrations less than one.
- Never follow a whole number with a decimal point and a zero (trailing zero).
- Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to "fax noise." Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

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- Code of Federal Regulations 21 lists hospice programs as one of three exceptions to the written prescription requirements for Schedule II controlled substances. This important exception was inadvertently omitted from the original Board rule and its addition is proposed.
- Hospital pharmacists are frequently authorized to follow in-house protocols approved by the pharmacy and therapeutics committee within their institution. Inpatient protocols are not subject to existing rules on collaborative practice. The words "non-institutional" have been added to clarify the requirements of 24.174.524.
- Many pharmacy technician tasks should be delegated by a pharmacist only to a pharmacy technician, however the Board agrees with practitioners that selling non-prescriptions drugs (24.174.705 f), checking incoming drug orders (24.174.705 i) and participating in a biennial inventory under a pharmacist's supervision (24.174.705 j) could safely be delegated to a clerk working in a pharmacy **unless** the pharmacist on duty for some reason objects.
- Montana is now the only state that limits the baseline technician to pharmacist ratio to 1:1. All other states now have maximum ratios of 1:2, 1:3, or 1:4; and some states have eliminated a recommended ratio entirely. No studies have linked the incidence of medication errors to increased ratios, but many studies have implicated increasing pharmacist workloads directly to increased rates of medication errors. The Board is proposing a maximum ratio of 1:4 in hopes that increased technician utilization and a corresponding decrease in the pharmacist's workload will help to prevent many medication errors while enabling the pharmacist to spend additional time in counseling patients and reviewing their medications. **It is important to note that if for any reason the pharmacist on duty feels that patient safety is not enhanced but potentially is harmed by an increased ratio, that pharmacist has the right and obligation to insist that a lesser ratio be utilized, and the Board will support that pharmacist if necessary.**
- Occasionally pharmacies have closed with no advance notice, creating patient safety issues when prescription refills cannot be obtained and the timing of previous refills is not readily available to the patient's physician or other provider. Prescriptions and patient refill history are required to be maintained for a minimum amount of time, and prescription information must be available to authorized board inspectors even though a pharmacy may have recently closed. The Board is proposing rules to address this.
- Montana Code Annotated 37-7-500-509 regulates drug product selection, giving the Board of Pharmacy authority to adopt, amend, or repeal rules to implement and enforce the section. As pharmacy benefit managers often engage in drug product selection that results in modification of drug therapy, they fall under the purview of the Board for regulatory purposes. The rule wording was made at the request of several citizens throughout the state, and was subsequently proposed by the Board to protect public health and safety.
- Many pharmacies presently maintain a Schedule II perpetual inventory to allow the earliest possible detection of errors, miscounts, or diversion of many of the most highly divertible medications. The Board proposes that all pharmacies maintain and routinely reconcile an ongoing written or electronic inventory of Schedule II controlled substances.

PSAM…how do you measure up?

The National Association of Boards of Pharmacy® has launched the Pharmacist Self-Assessment Mechanism™, an evaluation tool allowing pharmacists to test their knowledge base confidentially. It is available at www.nabp.net for a cost of $75.

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Rebecca "Becky" Deschamps, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

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